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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,362	01/19/2001	Solomon S. Steiner	PDC 119	8907

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EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/766,362

Applicant(s)

STEINER ET AL.

Examiner

Humera N Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Status of the Application**

Acknowledgement is made of the receipt of the request for an extension of time (1 month) and the response, both filed 04/10/02.

Claims 1-19 are pending. Claims 1-19 stand rejected.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11, 13-17 and 19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hettche (US Pat.No.5,164,194).

Hettche teaches a medicament composition for the nasal administration of a drug to a patient comprising azelastine in a dry powder form having a maximum particle size of 20 microns, suitable for local nasal application, which additionally overcomes the issues of bitter aftertastes and somnolence (see reference column 1, lines 34-68); (column 2, lines 1-34); (column 5, lines 18-53); (column 6, lines 1-35); (column 8, lines 1-46).

### ***Response to Arguments***

The applicant's arguments filed 04/10/02 have been fully considered, but are not found to be persuasive. The applicant argued that Hettche does not anticipate or disclose the applicant's particle size range of 10 to 20 microns; the examiner disagrees and points out that Hettche teaches a nasally administered composition wherein the particles are a maximum particle size of no greater than 20 microns. This provides for a range of anywhere between 0 to 20 microns. The instant claims are directed to a particle size range of 10 to 20 microns. The particle size range taught by Hettche reads on the applicant's range of 10 to 20 microns. Furthermore, the instant claims provide for a particle size range, rather than a specified particle size.

The applicant argued that the instantly claimed range is a much narrower range than the broad range of Hettche (0 to 20 microns). This argument is not found to be persuasive since the prior art teaches a maximum particle size of 20 microns, which meets the instantly claimed range of 10 to 20 microns. The teaching of a maximum particle size of 20 microns, also meets the applicant's objectives to retain particles in the nasal region, since Hettche teaches the same claimed ingredients and the same particle size range, therefore the properties would also be the same.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hettche in view of Feldstein et al. (US Pat.No.5, 352,461).

Hettche, while disclosing a medicament composition for the nasal administration of a drug comprising azelastine in a dry powder form, does not explicitly teach the use of the particular diketopiperazine polymer in his formulation. However, Feldstein et al. teach a drug delivery system in which diketopiperazine is used to form microparticles encapsulating a drug to be delivered (see reference column 2, lines 40-52); (column 3, lines 12-23); (column 5, lines 36-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a diketopiperazine polymer, which is highly stable and disintegrates easily in varying pH and is useful for oral delivery, with the expected result of obtaining a drug delivery system that can be made stable or unstable in a variety of physiological conditions.

### ***Response to Arguments***

The applicant argued that neither Hettche nor Feldstein provide an enabling disclosure of a dry powder formulation for nasal delivery, which requires the powder to stay in the nasal region. The applicant also argued that Feldstein teaches a particle size of 0.1 to 10 microns, which would pass through the nasal region. These arguments are not found to be persuasive, since the prior art teaches a dry powder nasal formulation, wherein the particles are specifically delivered to the nasal region. Hettche teaches a maximum particle size of 20 microns, which reads on the applicant's claimed

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range of 10 to 20 microns. Furthermore, the prior art of Feldstein was relied upon to demonstrate the use of a drug in a diketopiperazine formulation and was not relied upon for the particle size range, as Hettche initially met the applicant's particle size range of 10 to 20 microns.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600